IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC., Plaintiff, v. EXELA PHARMA SCIENCES, LLC, Defendant.	C.A. No. 22-1233-GBW

NEXUS'S OPENING BRIEF IN SUPPORT OF ITS POST-TRIAL MOTIONS FOR JUDGMENT AS A MATTER OF LAW AND FOR A NEW TRIAL

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Nexus moves for judgment as a matter of law under Rule 50(b) because the evidence was insufficient under the clear and convincing standard to support the jury's finding that claim 7 of U.S. Patent No. 11,464,752 ("the '752 patent") was invalid as obvious. Exela relied on materials without establishing what was available ***prior art*** (as opposed to non-prior art confidential information), it provided no ***motivation to combine*** references (as opposed to improperly using Nexus's patent claim as a roadmap to find elements), and it showed no ***reasonable expectation of success*** (as opposed to retroactively relying on Nexus's success).

Separately, Nexus moves for a new trial under Rule 59 because the verdict was against the great weight of evidence, Exela's persistent and impermissible inequitable conduct accusations irreparably tainted the resulting verdict, and in view of erroneous jury instructions.

I. NATURE AND STAGE OF PROCEEDINGS

The jury found that Exela willfully infringed claim 7 of the '752 patent, but found that claim invalid as obvious, along with verdicts on other claims. D.I. 358 at 1-2. Nexus previously moved under Rule 50(a) for a judgment of no obviousness. Tr. 1098:5-1099:24. Nexus also moved for mistrial on account of Exela's improper accusations of inequitable conduct. D.I. 330; Tr. 1099:25-1100:3. The Court denied Nexus's motions. Tr. 1120:18-1121:21.

II. SUMMARY OF THE ARGUMENT

Exela tried to establish only obviousness at trial, through its expert Dr. Myers (Exela's only expert permitted to offer POSA testimony), but its argument relied on patchwork pieces of disparate references. At trial, Exela presented three combinations: (i) Akovaz concentrate + Akers textbook, (ii) Akovaz concentrate + Akers textbook + CAPS, and (iii) Akovaz concentrate + Akers textbook + IntegraDose. Tr. 876:1-21; 1108:22-1109:7. Exela relied on the CAPS and IntegraDose compounded products as evidence of 5 mg/mL ephedrine sulfate syringes, but those syringes

contained only 8.1 mg/mL sodium chloride, had drug stability for just 90 days (CAPS) or 180 days (IntegraDose), were never terminally sterilized, and had never been tested for enantiomer levels. Tr. 639:6-8; 750:11-16; 905:4-6 (CAPS); 906:12-14 (IntegraDose); 1082:12-15.

Exela's hindsight-driven approach was underscored by its reliance on the Akers textbook in all three combinations. Akers is a general pharmaceutical textbook, not directed to ephedrine sulfate. DTX-240. Dr. Myers used it as a hindsight grab bag, conducting an impermissible limitation-by-limitation "seek-and-find" to locate snippets like "terminal sterilization" scattered across hundreds of pages. Obviousness requires much more. *See Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 887-88 (Fed. Cir. 2024) (noting mere assertions that claim elements are present in the prior art fails to "satisf[y] the motivation to combine analysis.").

III. CLAIM 7 OF THE '752 PATENT

Claim 7 of the '752 patent depends from claim 6 and independent claim 5. JTX-005 at 45:60-46:17. The full claim language is reproduced below:

> 5. A pharmaceutical product comprising:
> a packaged syringe containing a shelf-stable sterilized ephedrine composition comprising:
> a packaged concentration of ephedrine sulfate of 5 mg/mL;
> 9 mg/mL sodium chloride;
> water;
> no preservative;
> an initial pH level of about 4.5 to about 7; and
> having, after storage in the syringe at 25°C and 60% relative humidity for 12 months or after storage at 40°C and 75% relative humidity for 6 months:
> an ephedrine sulfate concentration of at least 95% of the packaged concentration, and
> a level of (+)-1S,2R-ephedrine not more than 0.5%.
>
> 6. The pharmaceutical product of claim 5, wherein the shelf-stable sterilized ephedrine composition is sterilized by terminally sterilizing the ephedrine composition in the syringe.

> 7. The pharmaceutical product of claim 6, wherein the step of terminally sterilizing comprises sealing the syringe and heating the sealed syringe at about 122°C for about 15 minutes.

IV. LEGAL STANDARDS

A court must grant judgment as a matter of law where it "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [the non-moving] party." Fed. R. Civ. P. 50(a)(1). In patent cases, the law of the regional circuit applies to JMOL motions. *InTouch Techs., Inc. v. VGo Comms., Inc.*, 751 F.3d 1327, 1338 (Fed. Cir. 2014). "[A] judgment as a matter of law must be sustained if the record is critically deficient of the minimum quantum of evidence from which the jury might reasonably afford relief." *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995). Where the non-movant (here Exela) bore the burden of proof, there is no need to also show "insufficient evidence for permitting any different finding." *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1333 (Fed. Cir. 2019) (quoting *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976)). A court may order a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a).

V. NEXUS IS ENTITLED TO JUDGMENT THAT CLAIM 7 IS NOT INVALID

A. Substantial Evidence Does Not Support A Motivation To Combine

Motivation to combine is a "critical component of an obviousness analysis." *InTouch*, 751 F.3d at 1351. In *InTouch*, the Federal Circuit reversed judgment after trial because the expert failed to "identify sufficient reasons or motivations to combine the asserted prior art references." *Id.* So too, here. Exela's witnesses "failed to identify any reason why one of ordinary skill in the art at the time of the invention would have sought to combine or modify the references." *Id.* at 1348.

This was Dr. Myers's testimony on motivation to combine Akovaz Concentrate with Akers:

> Q. Now, Dr. Myers, is there a reason why a person of ordinary skill in the art would have combined Akers and -- AKOVAZ and the Akers textbook prior to May of 2019?

> A. Yes.
>
> Q. Why -- why would a person -- a person of skill in the art want to do that?
>
> A. Because the concentrate product instructs you, teaches you how to make the diluted product, the diluted concentration, and the Akers tells you how to make it.

Tr. 912:8-16. Dr. Myers did not explain why a POSA would combine the product with Akers, or attempt to modify the label. After all, Nexus's invention did ***not*** simply follow the label instructions on a manufacturing scale. Tr. 275:10-279:2; 281:23-25; 290:5-291:23. Moreover, even looking at the label, Dr. Myers cherry-picked using the claimed sodium-chloride based option and not dextrose, which Exela tried but failed. Tr. 726:5-10. The Akovaz Concentrate product already existed as a manufactured product. Akers is an expansive 500-plus page textbook that includes myriad manufacturing options, but certainly was not about how to formulate or manufacture ephedrine sulfate. Tr. 956:20-958:1; 1018:13-23; 1019:8-22. Exela never explained why a POSA given the textbook and the already-manufactured concentrate products would have had any reason to change anything, much less in the claimed direction. DTX-240. Similarly, the CAPS and IntegraDose products were already sterile products. Tr. 893:9-13.

More broadly, Dr. Myers never explained why a POSA would want to make a ***manufactured*** 5 mg/ml product in the first place, essential to any motivation to combine analysis. Dr. Myers actually undermined any potential motivation to combine, by reporting that Akovaz Concentrate already met any need, precisely ***because*** the Akovaz Concentrate already came with instructions for how to separately add saline, dilute to 5 mg/ml, and that compounders already made such products. Tr. 938:18-22. Dr. Powell confirmed the same thing: no time delay issue, no safety issue, no sterility issue, no efficacy issue, and no shelf-life issue. Tr. 784:24-785:13; 787:25-789:13; 790:5-23, 797:21-25. Even today, Dr. Powell considers compounded syringes "safe, sterile, and effective." Tr. 797:21-25; 938:23-25. Expressly adopting Dr. Powell's testimony, Dr.

Myers went so far as to testify that "[i]t's just not true" there was any need to change the prior art. Tr. 939:1-4. These facts show "no perceived benefit" in the prior art to the claimed invention, which is "inconsistent with a motivation to combine," and defeats obviousness. *Tris Pharma, Inc. v. Actavis Labs. FL, Inc.*, Case No. 2021-1495, 2022 WL 2525318, at *4 (Fed. Cir. July 7, 2022).

Even if a POSA would have considered manufacturing a 5 mg/mL product with saline—as opposed to following the label or relying on compounders—Dr. Myers never explained why a POSA would combine references (without regard to Nexus's reasoning), such as a teaching, or a design incentive, or market forces. *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 417-419 (2007). Exela left unanswered critical questions including: Why would a POSA consider Akers in particular (it does not talk about ephedrine sulfate)? If a POSA did consider Akers then why select a terminal sterilization process (as opposed to aseptic)? And if a POSA did consider terminal sterilization why the specifically claimed conditions (as opposed to a different time/temperature)? Indeed, all the compounders including CAPS and IntegraDose used aseptic processing to make a sterile product and ***not*** terminal sterilization. Tr. 824:22-825:7; 1082:12-15; DTX35.6-10; DTX26.11-20. On their face, Exela's proposed combinations are therefore incompatible. Akers itself describes "small-scale processes" like hospital pharmacies or compounding as distinct rom "large-scale processing" for manufacturing, making them mutually exclusive. DTX-240.191.

Dr. Myers all but conceded hindsight for these questions, testifying that Akers was a generic reference that "has all the good stuff in it on how to do the development of these [sterile] products," Tr. 868:2-15, and that Akers included information about "sterile products, sterile manufacturing" generally. Tr. 876:16-21. He completely ignored, however, entire sections from Akers on aseptic processing, even though that is what he himself had used for ephedrine sulfate. DTX-240 at 324-38. He testified that the compounders' aseptic process was enough to achieve

"sterile" formulations. Tr. 867:21-868:3. Nevertheless, Dr. Myers cherry-picked language from disparate parts of Akers, homing in on claimed sealing containers from one chapter, using autoclaves from a glossary, and stability testing conditions from yet a different section. Tr. 909:4-7 (Akers page 195), Tr. 909:17-19 (Akers page 14), Tr. 913:24-914:4 (Akers page 374). The hindsight was clear: Dr. Myers started with the terminal sterilization claim term and worked backwards to "take a look and see what Akers says about terminal sterilization.' Tr. 908:19-909:12.

Exela's analysis breaks down even further for the other proposed combinations, Akovaz Concentrate and Akers with CAPS or IntegraDose:

> Q. And would a person of ordinary skill in the art looking to make a diluted ephedrine sulfate formulation based on the AKOVAZ label have reason to look at CAPS and IntegraDose?
>
> A. Certainly, yes.
>
> Q. Why so?
>
> A. Because they were already there, already existing pre-filled syringes.

Tr. 912:17-24. The testimony never answers the question ***why*** a POSA would look to combine or modify something that was already there? Of course the compounded products existed. As in *InTouch*, Dr. Myers failed to explain "what reason or motivation one of ordinary skill in the art at the time of the invention would have had to place these pieces together." 751 F.3d at 1349.

Dr. Myers impermissibly relied on the patent itself as a roadmap to show obviousness for terminal sterilization and autoclaving. *InTouch*, 751 F.3d at 1351. He started with the claim for "what is required by claim 7," and then worked backwards to address "have you seen anything that describes the requirements of [claims 6 and 7] in the prior art?" Tr. 907:21-908:5. Similarly, for the "terminal sterilization" claim term, Dr. Myers first looked at claim 6 and then addressed the question "[i]s this a normal technique?" Tr. 908:19-909:3. Mr. Cohen described various available options. Tr. 284:10-285:6. Dr. Myers used ore hindsight to pick "autoclaving" despite

other available alternatives, and being led specifically to "page 14" with no other reason or context than the claim required autoclaving. Tr. 909:17-910:8.

Exela failed to prove where a POSA would find and why they would be motivated to use the specifically-claimed sterilization conditions of autoclaving a syringe at 122°C for 15 minutes. As Nexus's scientist Ms. Jagdeep Kaur testified, compounders were known to use aseptic, and not terminal sterilization by heat. Tr. at 824:22-826:12. Exela offered no evidence that any syringes—whether following the label instructions or not—were ever terminally sterilized, or ***could*** have been terminally sterilized under these conditions. Nor did Exela offer evidence that CAPS or IntegraDose terminally sterilized, or even ***could*** have done so for their syringes. Tr. 1081:24-1082:15; DTX35.6-10; DTX26.11-20.

Dr. Myers used hindsight again to find *anything* that was terminally sterilized, this time pointing to the Akovaz Concentrate internal confidential process for making 50 mg/ml vials. Tr. 911:7-22. The Akovaz Concentrate internal confidential process was never published, however, and Exela offered no basis to show why that process was prior art, much less how it could have applied to make a different product with a different formulation, concentration, and container. Tr. 866:17-867:2; 952:21-953:18; DTX-236.1, 6. Dr. Myers knew that terminal sterilization was not a universal standard; he testified that autoclaving times and temperatures "are individualized" process steps that "you would have to validate." Tr. 910:17-25. Dr. Myers never showed—at least not without hindsight—why any POSA would have thought to use terminal sterilization with a pre-filled syringe, much less autoclaving at 122°C for 15 minutes.

Dr. Myers also provided no basis for why or how a POSA would have sought a "packaged" syringe. He only declared that CAPS and IntegraDose were packaged, with no explanation. Tr. 892:21-893:3. Once again, Dr. Myers ticked off claim limitations without evidence.

In sum, Dr. Myers used the patent claim terms as a shopping list, against which to "check off" limitations anywhere in any of the alleged prior art. His testimony "was nothing more than impermissible hindsight; [he] opined that all of the elements of the claims disparately existed in the prior art, but failed to provide the glue to combine these references." *InTouch*, 751 F.3d at 1348; *see also ActiveVideo Networks, Inc. v. Verizon Comms., Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (quoting *KSR*, 550 U.S. at 418) (affirming JMOL overturning jury verdict of obviousness).

B. Substantial Evidence Does Not Support Akovaz Concentrate, CAPS, and IntegraDose Confidential Testing Data Were Prior Art

Exela's clear and convincing burden applies not only to the obviousness argument, but also to "all issues relating to the status of [alleged prior art] as prior art." *Mahurkar v. CR Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). Exela relied on internal confidential information especially for two key claim terms: (a) 0.5% enantiomer (Akovaz Concentrate) and (b) 95% ephedrine sulfate concentration (Akovaz Concentrate, CAPS PFS, and IntegraDose PFS).

Akovaz Concentrate testing data was labeled as confidential and produced as such. DTX-1.15653. Later 48-month tests were not designated confidential, but there was no evidence they were ever publicly available, DTX-325, and that document is dated from 2021 (so could not be prior art). CAPS PFS (e.g., DTX-25) and IntegraDose PFS (e.g., DTX-26) were both designated and produced as confidential. No jury instruction permitted considering confidential non-prior art information for obviousness. Yet Dr. Myers's testimony relied on these non-prior art materials. Tr. 884:11-886:10; 888:14-889:7; 903:20-904:4; 905:12-906:11; 918:10-25; 919:8-920:16.

Exela did not prove confidential Akovaz Concentrate information was prior art. Nexus's expert, Dr. Fix, confirmed that the Akovaz Concentrate testing data was confidential, and would not have been available to the POSA. Tr. at 1007:9-23. The only alleged prior art enantiomer data Exela offered at trial was the non-public Akovaz Concentrate data. Tr. 900:4-5; 900:16-901:9;

905:4-6; 906:12-14. Exela did not meet its burden to prove any prior use or prior sale. In fact, Dr. Myers conflated the alleged prior art related to the "Akovaz Concentrate," sometimes referring to an Akovaz label (DTX-330), but mostly referring to an "Eclat" product label (DTX-236), while Dr. Koneru separately referred to a sales spreadsheet relating an "Eclat" tab (DTX-320). No one connected any dots regarding "Eclat." Exela did not meet its burden to connect a ***particular*** product with ***particular*** data, so could not assume that available data related to something actually used or sold. Even if Exela could have shown a use or sale of a particular product, test results were still never public, so they are not prior art. *Dey, L.P. v. Sunovion Pharms., Inc.*, 715 F.3d 1351, 1355, 1359 (Fed. Cir. 2013) (reversing summary judgment without evidence public had "the claimed features of the invention in the allegedly invalidating prior art"). Exela also failed to prove that the various materials it swept under the "Akovaz Concentrate" rug actually reflected one prior art reference—including different labels, products, testing data, internal procedures, and the USP. *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1351 (Fed. Cir. 2008).

Exela relied heavily on CAPS and IntegraDose internal confidential data, without proving it was prior art or that various materials reflected one reference. Dr. Fix explained CAPS testing was not publicly available information. Tr. 1011:4-23; 1013:16-17; 1014:3-13; 1016:21-1017:9; 1017:15-24. In addition, for CAPS, Dr. Myers admitted that he relied on confidential data "not publicly available." 966:11-967:6; 967:18-22. That should end the prior art inquiry. To the extent that Exela was trying some other way to rely on that data, Exela never tied it to anything actually sold. *Exela Pharma Scis., LLC v. Eton Pharms., Inc.*, 620 F. Supp. 3d 108, 129-130 (D. Del. 2022). Exela did not offer any CAPS sales reports. Instead, it relied on the testimony of CAPS's deponent Mr. Jones that some 5 mg/ml syringe product was offered for sale, but he was not sure if any product was actually sold before the priority date, and did not link any product potentially offered

for sale to any actual testing data. Tr. 762:24-763:20; 763:21-23; 770:7-771:4, 771:13-14. Mr. Jones discussed CAPS catalogs from 2017 and 2018. Tr. 762:23-763:1; 770:7-10; DTX-33.6; DTX-41.6. But those catalogs did not reflect an offer for sale, because they did not contain binding terms like price and quantity. *Grp One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001) (requiring an offer to reflect "a binding contract by simple acceptance"). Nor were they proof of use, since it was not clear what was available. Mr. Jones separately discussed a range of documents, but did not connect them to show prior art status: a product catalog from November 2018, separate testing data from 2015, and a series of formula records from 2023. Tr. at 760:20-763:1, 763:23-764:7. Dr. Myers never connected these dots either. Tr. 881:20-22, 882:21-883:11. Mr. Jones did not know if the product listed in the catalogs had the inactive ingredients described in the drug master formula, or met any particular product specification. Tr. 762:24-763:23; 764:5-13; 764:22-25; 765:18-766:25; 770:7-771:14. In fact, Exela never showed what starting material any compounder used to make any product. At best, Mr. Jones testified that CAPS purchased "ephedrine sulfate concentrate vials" at some point "in the past." Tr. 771:25-772:10. Dr. Emamifar explained that CAPS did not always use the same process, so it was impossible to connect the dots between various CAPS materials. Tr. 1086:5-11; 1087:21-23; 1088:4-1089:12.

There was even less evidence about IntegraDose as prior art. Dr. Myers admitted that IntegraDose testing data "were not publicly available." Tr. 967:23-969:3. Exela presented no testimony about alleged prior sales or uses, and the Court properly denied Exela's pretrial plan to offer a hearsay declaration by Mr. Craig Else. D.I. 329, at 5. Exela thus relied on a catalog, which again could not be considered an offer for sale or proof of use. DTX-26.203. Exela's failure to prove prior art status is significant, because IntegraDose was the only compounded product that had allegedly been tested for 180 days, unlike the 60-90 days for all others.

C. Substantial Evidence Does Not Support A Reasonable Expectation Of Success

Another essential evidentiary requirement to find obviousness is a reasonable expectation of success that the purported combinations would have worked for its intended purpose. *Endo Pharms. Inc. v. Actavis LLC*, 922 F.3d 1365, 1373 (Fed. Cir. 2019). In fields such as drug development, an expectation requires concrete data, as opposed to "no more than hope." *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1384-85 (Fed. Cir. 2019). For example, there is no reasonable expectation of success when prior art data relates to a different dosage form. *Galderma Lab'ys, L.P. v. Sun Pharms. Indus. Ltd.*, 411 F. Supp. 3d 271, 315 (D. Del. 2019).

Dr. Myers gave conclusory testimony about any reasonable expectation of success:

> Q. Okay. For Claim 7 of the '752 patent, would a person of ordinary skill in the art have a reasonable expectation of success of arriving at the claimed product?
>
> A. Yes.

Tr. 928:11-14. Exela's absent evidence was countered by the published Storms article regarding 5 mg/ml ephedrine sulfate formulations, which added a preservative to help aid stability, while claim 7 requires "no preservative" formulations. DTX-253.1, Tr. 933:25-934:3. Dr. Myers did not provide sufficient basis why a POSA would have had an expectation of success for several reasons.

First, through any of its combinations, Exela failed to articulate any reasonable expectation of success for terminal sterilization of a pre-filled syringe with the claimed formulation. Not everything can undergo terminal sterilization. Tr. 285:16-286:1. Akers itself reported that terminal sterilization may be considered only "if possible" and in connection with freeze-dried products. Tr. 924:14-925:3; DTX-240.195. Dr. Fix explained the same thing, and Exela did not bother to rebut his testimony. Tr. 1018:24-1019:22. Exela's CEO Dr. Koneru admitted that any alleged 5 mg/ml prior art formulation had 8.1 mg/mL sodium chloride and not 9 mg/mL sodium chloride, because of differences in how they were made. Tr. 639:2-20. Akovaz Concentrate was not in a

syringe, and had 50 mg/ml ephedrine sulfate, and no sodium chloride. Tr. 911:13-19; 952:25-953:18. Dr. Myers never testified that a POSA would have had any reasonable basis to expect terminal sterilization to work on the claimed formulation, despite acknowledging the differences. Tr. 953:14-18. Dr. Myers conceded that FDA required Exela to test its formulation, to account for differences in formulation and container despite owning Akovaz Concentrate data. Tr. at 991:4-12. Nexus's Mr. Cohen explained how Nexus developed a product that had to take formulation and container interactions into account. Tr. 276:23-277:8.

Second, Dr. Myers never offered evidence that a POSA would have reasonably expected the specifically claimed terminal sterilization criteria to work: applying 122℃ for 15 minutes. Dr. Fix provided unrebutted testimony that no 5 mg/mL prefilled syringe underwent terminal sterilization until Nexus's invention. Tr. 344:24-345:22; 1082:12-15. As noted above, there was no evidence that any prior art syringe—including the syringes compounders used—***could*** undergo terminal sterilization, much less at these conditions. Tr. 639:21-640. To the contrary, Exela told the FDA that compounders used a "syringe that is quite inexpensive and understood to be having unacceptably high levels of extractables/leachables." Tr. 642:4-9; PTX-109.7. Exela thus had to prove to the FDA that the terminal sterilization had no effect on the syringes, and "we assessed both terminally sterilized and nonterminally sterilized presentations." Tr. 723:10-22.

Third, Exela did not show a POSA would have had a reasonable expectation of success to meet the 0.5% enantiomer limitation. CAPS and IntegraDose never tested enantiomer levels, not even on day zero. Tr. 905:4-6; 906:12-14; 1013:16-1014:13; 1016:21-1017:24; DTX-25.7-12; DTX-26.321-360. Dr. Myers admitted that CAPS and IntegraDose did not test for enantiomer content, so he relied upon Akovaz Concentrate's internal testing:

Q. Did the CAPS company test the CAPS pre-filled syringe for the enantiomer?

> A. No, they did not.
>
> Q. But would you expect the enantiomer content to be more than 0.5 percent under the claimed conditions?
>
> A. Not necessarily because this product was made from the concentrate product, which was shown to not have the enantiomer.
>
> …
>
> Q. Did IntegraDose -- was the IntegraDose pre-filled syringe tested for enantiomers?
>
> A. No, it was not.
>
> Q. Would you expect the enantiomer content to be more than 0.5 percent under the patent claimed conditions?
>
> A. No, for the same reason, it's made from the concentrate product.

Tr. 905:4-11; 906:12-18; *see also* 900:16-23; 902:18-22. As is clear, Dr. Myers only testified about his own expectation ("Would you expect"), and not what a POSA would have considered.

Substantial evidence showed that a POSA would not have had any reasonable expectation of success for meeting the claimed enantiomer levels. Enantiomers were known to interconvert, and Exela never explained why or how a POSA would expect the claimed level. Tr. 279:21-281:7; 365:13-366:24. Even though it had Akovaz Concentrate data, Exela told FDA that it had to test the "critical quality attribute" of "degradation product C," which "is an enantiomer of ephedrine." PTX-1354.14-15; Tr. 653:4-654:19. Similarly, when Nexus submitted its FDA application, FDA required enantiomer testing. Tr. 830:12-832:1; DTX59.2. A sensitive test for enantiomers in this formulation did not exist; Nexus had to develop its own. Tr. 281:8-25; 831:11-23.

Fourth, assuming the POSA could access confidential data, Exela still could not show a reasonable expectation of success. Especially for the 95% drug stability and 0.5% enantiomer limitations, Exela had to prove that a POSA would have had a reasonable expectation of success to meet them as part of the combination of claimed elements, or that these were inherent properties.

Exela did neither. Instead, Exela presented isolated data, without justifying how it could be applied despite all of the differences in formulation, concentration, and container. Tr. 1005:11-1006:16; 1007:24-1008:12. Dr. Myers admitted the same. Tr. 991:4-12. Exela never rebutted Dr. Fix's testimony about the formulation differences between 50 mg/ml and 5 mg/ml, on variables including formulation stability. Tr. at 1006:13-1007:8, 1008:13-1009:13. Neither CAPS nor IntegraDose tested for enantiomers, and were not tested for any variable for the claimed 12 months. Tr. 904:17-18; 906:1-2; 1013:16-1014:13; 1016:21-1017:24; DTX-25.7-12; DTX-26.321-360.

Moreover, the limited CAPS and IntegraDose data was not validated, and therefore unreliable. Tr. 288:16-289:17; 1011:24-1012:23; 1017:3-14. Exela agreed that compounded syringe data was prepared "with unknown but suspected to be non-ICH-complying quality attributes." Tr. 644:6-20; PTX-109.9. And as they drilled home during Dr. Fix's cross-examination, everything must be tested with its own set of variables to know whether or not it worked for its intended purpose. Tr. 421:7-20; 422:10-423:24; 424:7-13; 427:17-429:2.

Exela did not attempt any showing of inherency either; it never even mentioned the term. Meeting inherency requires showing an element is necessarily and always present, a very exacting standard. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014). Moreover, to rely on inherency, Exela must have further shown that the claim element was not unexpected. *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, 865 F.3d 1348, 1354-55 (Fed. Cir. 2017). Exela made no such showings.

Fifth, Exela also never addressed the specific manufacturing steps that contributed to the claimed stability and enantiomer results, including the materials and sources. Tr. 1077:18-1082:15. The '752 patent disclosed and taught how to make and use the claimed invention, and before that, no one had done it. Tr. 361:25-362:4; PTX-55. Exela did not show that data from

some other process (whether Akovaz Concentrate or CAPS/IntegraDose) would have had no effect on the claimed drug stability or enantiomer levels. *Exela*, 620 F. Supp. 3d at 127-28, 140-41.

Sixth, mere months before the priority date of Nexus's patents, Exela itself confirmed why a POSA would not have had any reasonable expectation of success. Exela told the FDA that it was "unsure how the product stability profile would present itself." Tr. 640:2-641:14; 642:20-643:19; PTX-109.7-8. Before the bias of litigation, Exela readily admitted that prior art compounded products were of "unknown quality" with shelf lives based on "assay value and not based on ICH guidelines for stability and shelf-life assignment." Tr. 641:22-642:3; 644:6-20; PTX-109.8-9. Exela further acknowledged it was not sure if it could achieve 6 months stability, much less the claimed 12 months. PTX-109.8, Tr. 643:9-644:5. The jury had no evidence to find otherwise.

D. JMOL Is Required Because Obviousness Cannot Stand When Exela's Witnesses Failed To Consider Or Rebut Secondary Considerations

Exela did not show a *prima facie* case of obviousness, but even if it had, Exela elected not to rebut Nexus's evidence of secondary considerations, precluding a finding of obviousness. Although labeled "secondary," the burden of persuasion to show obviousness required Exela to incorporate all objective indicia of secondary considerations. *In re Cyclobenzaprine Hydrochloride*, 676 F.3d 1063, 1077-78 (Fed. Cir. 2012). The Court set four rounds of proof in the Pretrial Order, with Round 3 including secondary considerations, and Round 4 permitting Exela to rebut secondary considerations. D.I. 321 at 26, ¶ 94. Nexus met its burden of production, with detailed testimony by Dr. Fix and Dr. Emamifar regarding nexus and secondary considerations, including unexpected results with two-year stability (Tr. 1021:20-1024:9; 1027:10-1028:7), failure of others with Exela's 10 mL and dextrose (Tr. 649:8-650:5; 726:5-10), and licensing acknowledging the '752 patent is valid (Tr. 205:17-206:7; PTX-1552.5). "[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence

is tied to a specific product." *WBIP, LLC v. Kohler Co*., 829 F.3d 1317, 1329 (Fed. Cir. 2016). Exela waived Round 4, and did not rebut secondary considerations. Tr. 1094:19-20.

Dr. Myers addressed long-felt need out of turn, but that only undercut any assertion of motivation, as discussed above. Dr. Myers also alleged Exela's own alleged secondary consideration of independent near-simultaneous invention, but that evidence was far too little, and Exela's work too late. The jury found Exela willfully infringed, D.I. 342 at 3, and Exela's work was filed a year and half after the priority date, DTX-283 (pre-IND without any data); Tr. 735:19-21 (Exela sNDA with data filed 10/10/20); *see* D.I. 322-3 (Nexus's MIL #3). Ultimately, Dr. Myers shirked the responsibility to "guard against [] hindsight bias by appropriately considering all objective evidence of nonobviousness" so his analysis was "incomplete and ultimately insufficient to establish obviousness." *InTouch*, 751 F.3d at 1352.

VI. A NEW TRIAL SHOULD BE GRANTED REGARDING CLAIM 7

A. Great Weight Of Evidence Showed Claim 7 Would Not Have Been Obvious

If judgment is not entered in Nexus's favor on obviousness, then Nexus seeks a new trial based on the absence of evidence of obviousness. The judge need not infer facts in Exela's favor for this motion, and may grant a new trial where "a miscarriage of justice would result if the verdict were to stand." *Roebuck v. Drexel Univ.*, 852 F.2d 715, 735-37 (3d Cir. 1988). For substantially the same reasons as addressed above for JMOL, a new trial is warranted. *See Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1187-88 (Fed. Cir. 2002) (affirming new trial on obviousness where evidence did not support verdict).

B. Exela's Baseless Accusations That Nexus Withheld Information From The Patent Office Undermined Nexus's Right To A Fair Trial

Exela contaminated the record before the jury with its aggravated and persistent accusations that Nexus withheld CAPS and IntegraDose prior art. Under Third Circuit law, a new

trial is proper for such prejudicial remarks because it is "reasonably probable" those prejudicial remarks influenced the jury's verdict. *Draper v. Airco, Inc.*, 580 F.2d 91, 96-97 (3d Cir. 1978).

Exela converted a borderline proper argument (that certain references were not before the Patent Office) into a clearly improper argument (that Nexus knew about or withheld those references). The latter argument sounds in inequitable conduct, that "the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). But inequitable conduct was never part of this case. It was not in the pleadings, much less the Pretrial Order; even if it were, it would have been an equitable claim for the judge and not the jury. *Freshub, Inc. v. Amazon.com, Inc.*, 93 F.4th 1244, 1246 (Fed. Cir. 2024). Obviousness, on the other hand, was supposed to be presented from an objective standard, what the hypothetical POSA would have considered obvious based on the prior art. *Graham*, 383 U.S. at 3. It is completely irrelevant—and prejudicial—whether or not Nexus knew about any prior art. *See, e.g., Waddington N. Am., Inc. v. Sabert Corp.*, No. 09-4883 (GEB), 2011 WL 3444150, *9 (D.N.J. Aug. 5, 2011) (granting motion for new trial because when "no inequitable conduct claim exists in a case, it is improper for a party or the Court to cast aspersions on the validity of the patent based upon improprieties in the prosecution of the patent."); *see also Novo Nordisk A/S v. Becton Dickinson & Co.*, 304 F.3d 1216, 1220 (Fed. Cir. 2002) (requiring "careful scrutiny" for inflammatory insinuations).

Exela nevertheless alleged Nexus "hid" prior art in its opening statement. Tr. 157:2-8; 178:13-179:2. It presented demonstratives to the jury that Exela never disclosed beforehand, despite the Pretrial Order. D.I. 321, at 16, ¶ 53. Nexus objected to the improper assertion immediately after the opening. Tr. 183:21–186:17. Yet Exela went back to the same accusation during Ms. Ahmed's testimony. Tr. 225:14-16; 226:11-13; 230:2. Nexus objected again, and the

Court sustained the objection (Tr. 225:17-19), and warned Exela's counsel. Tr. 267:19-269:5.

Nexus moved for a mistrial. D.I. 330. The Court denied the motion, but recognized that it "had already warned counsel for Exela, in a side bar, that she should not make statements or ask questions that sound in inequitable conduct." D.I. 332, at 2. The Court also permitted a curative instruction. *Id*. at 6. But Exela still did not stop. During the cross-examination of Dr. Fix, Exela's counsel asked about prosecution history statements, and when Nexus objected, the Court warned Exela during sidebar "don't refer to anything being withheld from the PTO" and "stay away from inequitable conduct." Tr. 1052:1-9; 1053:11-15. While that counsel avoided those express words, the only inference that he conveyed to the jury was that Nexus withheld information: questions about CAPS and IntegraDose were sandwiched between Nexus's statements in the prosecution history. Tr. 1053:21-1058:1.

At closing argument, Exela once again returned to its inequitable conduct theme. It showed a side-by-side comparison with allegations on one side from the 2020 compounder litigations about 2020 product information (again, ***not prior art***) and on the other side arguments patent counsel made to the patent office. Tr. 1203:21-1206:4. Exela invoked the very objected-to testimony by Ms. Ahmed that caused the problem. Tr. 1204:1-5. Not only was this irrelevant, prejudicial, and contrary to the Court's Order, it was also untrue. The CAPS and IntegraDose "prior art we're talking about" was not prior art. Exela had aggressively questioned Ms. Ahmed about allegations from unrelated litigation against CAPS (IntegraDose was not named) that referenced a CAPS catalog listing from 2020, (Tr. 215:9-21; DTX-265.22 at ⁋ 70), well after the May 2019 agreed priority date, D.I. 321-1 at 5. And there is no evidence that Ms. Ahmed had any confidential information from CAPS or IntegraDose—she was not named on the Protective Order. Yet Exela still implied that she did. Tr. 222:16-223:9; 224:14-225:20; 227:17-230:5.

The facts warrant a new trial. The Federal Circuit recently reversed a district court's denial of a motion for a new trial, where counsel infected the record with improper and prejudicial theories. *Magēmā Tech. LLC v. Phillips 66*, -- 4th --, 2025 WL 2586180 (Fed. Cir. Sep. 8, 2025). There, the defendant during litigation took the position that the patentee "did not need actual testing samples to prove infringement," but at trial argued that actual testing ***was*** required. *Id*. at *3-*4. The Federal Circuit held that "we have little confidence that those arguments did not affect the outcome of the trial." *Id*. Similarly, in *Pavemetrics Sys., Inc. v. Tetra Tech, Inc.*, 652 F. Supp. 3d 1098, 1103–04 (C.D. Cal. 2023), the court granted a motion for new trial because questions and argument related "to purported inequitable conduct" even though "both sides agreed that inequitable conduct was not an issue in the case."

Although the Court gave a curative instruction, it erred by not giving Nexus's proposed instruction and by not giving the curative instruction in real time, instead of waiting until the end of trial where it was buried with all other instructions. D.I. 360. For the content, Nexus requested that the instruction to explicitly note that "I have ruled that Exela's statements were improper and should not have been made" and that not only comments but also any "evidence" should be disregarded about allegedly withheld information. The Court declined to include these proposals. Tr. 1150:2-1151:15. Nexus also requested the Court to give the instruction contemporaneously, but the Court declined, instead including the instruction with the full set given to the jury, thereby diluting its potentially curative effect.

There was no special interrogatory and only the general finding of obviousness (D.I. 342, at 4), so a new trial is required because "we cannot tell why" the jury reached its decision. *Magēmā*, -- F.4th --, at *8. Given the prejudicial effect of the evidence and argument about inequitable conduct, a new trial is warranted.

C. Jury Instruction Errors Prejudiced Nexus

In addition to the curative instruction errors, two others prejudiced the outcome. First, for Instruction 5.3 on "Obviousness," the Court did not accept Nexus's proposal that not only the patent but also "products implementing the patent" cannot be used as a roadmap to find obviousness. Tr. 1134:3-1135:4; D.I. 333 at 12-13. Second, for Instruction 5.3.2 on "Differences Between the Claimed Invention and the Prior Art," the Court rejected Nexus's entire proposal that

> A person of ordinary skill in the relevant field would not combine the teachings of prior art references to obtain the claimed invention when doing so would require combining teachings that are incompatible with each other, that would require alterations to one of the references that would fundamentally change its principle of operation, or that would disregard a distinguishing characteristic.

Tr. 1135:5-1136:2; D.I. 333 at 14-16. The Court's only reasoning for rejecting both instructions was that they are not found in a model instruction. *Id*. But both statements were accurate and important statements of law, in the context of this case and Nexus provided supporting case law citations. The absence of these instructions prejudiced Nexus at trial. Exela argued, and the jury could have relied on, Nexus's own product as a roadmap to what a POSA would have done, even though that is improper. And Exela argued, and the jury could have relied on, whether disparate references render the claims invalid—despite technical infeasibility or incompatibility.

D. Nexus Is Entitled To A New Trial Because Of The Cumulative Effect Of These Errors

Even if any individual error does not rise to the level of a new trial, the combined effect of all these above errors does, and the Court should therefore grant a new trial.

VII. CONCLUSION

For all the above reasons, the Court should grant judgment as a matter of law that claim 7 of the '752 patent is not obvious and schedule a damages trial. In the alternative, the Court should grant a new trial on obviousness and damages.

/s/ Christine D. Haynes

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